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Biodiplomacy: A Better Approach to Dual Use Concerns

Victoria Sutton
Texas Tech University School of Law, vickie.sutton@ttu.edu

BIODIPLOMACY: A BETTER APPROACH TO DUAL USE CONCERNS

VICTORIA SUTTON*

I. INTRODUCTION

Biological materials and research with the power to save lives, as well as the power to take them, have been deemed "dual use" technologies, research, or materials. The United States Centers for Disease Control and Prevention (CDC) has created a program known as "dual use research of concern" (DURC) as a way of creating a category for increased surveillance and scrutiny of these activities. The National Institutes of Health (NIH) has adopted DURC as a process they will use when soliciting grants and awards involving research that may meet this definition.[1] The definition of DURC from the National Science Advisory Board for Biosecurity (NSABB) is a good starting point. The definition is limited to research, but many other activities like manufacturing or translational activities could otherwise be dual use activities. The definition is as follows: "research that, based on current understanding, can be reasonably anticipated to provide knowledge, products, or technologies that could be directly misapplied by others to pose a threat to public health and safety, agricultural crops and other plants, animals, the environment or materiel."[2]

Internationally, the term has also been used as a focus for safeguarding research. The United Nations Biological and Toxin Weapons Convention (BWC) has included dual use monitoring as a possible Confidence Building Measure (CBM) to show party compliance.[3] The Global Alert and Response

* Paul Whitfield Horn Professor, Texas Tech University School of Law and Director of the Center for Biodefense, Law and Public Policy. This work was supported in part by NIH Grant no. 5 U54AI057156-10.

1. NAT'L INST. OF HEALTH, NIH POLICY ON MITIGATING RISKS OF LIFE SCIENCES DUAL USE RESEARCH OF CONCERN (2013).

2. NAT'L SCI. ADVISORY BD. ON BIOSECURITY, PROPOSED FRAMEWORK FOR THE OVERSIGHT OF DUAL USE LIFE SCIENCES RESEARCH: STRATEGIES FOR MINIMIZING THE POTENTIAL MISUSE OF RESEARCH INFORMATION 17 (2007).

3. Kelsey Gregg, *Compliance with the Biological and Toxin Weapons Convention (BWC)*, THE FED'N OF AM. SCIENTISTS (Aug. 3, 2010), http://blogs.fas.org/blog/2010/08/compliance-with-the-biological-and-toxin-weapons-convention-bwc/.

(GAR) program of the World Health Organization (WHO) has also adopted a DURC program component.[4]

Despite its widespread popularity as a term upon which to hang a program, this kind of focus may prove to have shortcomings. First, the use of this term has the result of shifting the presumption to the scientist to prove that the research will not be used to harm, and it creates an atmosphere of suspicion in a culture of research that has always been open and sharing. Second, it presumes that dual use biological materials can be identified to warrant this special treatment. Both of these shortcomings may distract from many other aspects of biosecurity if DURC is relied on as the primary method for controlling biological research and materials. Communication and collaboration may be better tools for monitoring and understanding the risks and should not be minimized in favor of the ease of using a "catchy" term. Biodiplomacy is that package of considerations that might prove to be more useful in meeting the goal of global biosecurity by including dual use, but not focusing on it as a centerpiece for a policy.

The use of the term "biodiplomacy" is a kind of diplomacy, unique in its need to treat biological research and commercial activities with the kind of control that will prevent catastrophic consequences from misuse. The term takes the traditional meaning of the term public diplomacy,[5] and applies it to this unique area. The traditional meaning was once articulated by former diplomat Edmund A. Gullion in 1966: "By public diplomacy we understand the means by which governments, private groups and individuals influence the attitudes and opinions of other peoples and governments in such a way as to exercise influence on their foreign policy decisions."[6] But with time, the definition has come to embrace both the means as well as the results, and also includes actions taken domestically in response to pressures from international relations.

The term "biodiplomacy" also extends to the strategy by which governments, private groups, and individuals influence the attitudes and opinions of other peoples and governments to create domestic and foreign policy concerning biological materials, equipment, and facilities to prevent making, using, or producing biological weapons. This is not required by the BWC, and the need to influence domestic policy with regard to individuals,

4. *See Dual Use Research of Concern (DURC)*, WORLD HEALTH ORG., http://www.who.int/csr/durc/en/ (last visited Oct. 21, 2013).

5. *Definitions of Public Diplomacy*, TUFTS FLETCHER SCHOOL, http://fletcher.tufts.edu/Murrow/Diplomacy/Definitions (last visited Oct. 21, 2013). The Fletcher School identifies the roots of public diplomacy originating in the 1960s but concludes that it has grown in scope beyond its traditional meaning. "Today it goes far beyond a classical definition involving how elected and appointed government officials communicate, argue and influence policies publicly to a more two-pronged concept involving cause and effect." *Id.*

6. *Id.*

non-governmental organizations, and businesses in order to safeguard its life sciences could be accomplished through biodiplomacy.

The definition of diplomacy implicitly includes "trust" as part of a strategy to encourage individuals and governments to be influenced by our views. In appealing to either a self-interest (in the case of an autocracy) or national interest (in the case of a democracy), a degree of trust is essential to make a convincing appeal in diplomacy. A diplomatic agreement is nothing more than a covenant of trust in a social contract between nations. The statement made by President George W. Bush after his first meeting with President Putin of Russia rings of that search for trust between nations when he expressed a mutual trust that came when he looked into his eyes and "was able to get a sense of his soul."[7]

Trust is also implicit in biodiplomacy, particularly where dual use concerns are at stake. Any suggestion of a lack of trust is fatal to a diplomatic social contract of mutual trust. So it follows, standards that suggest a nation cannot be trusted with biological materials, equipment, and facilities fail because they are rife with notions of untrustworthiness. Many biological materials, facilities, and equipment can have both malevolent and good uses, but deeming all of them suspect makes for a rocky start to biodiplomatic relations. The inescapable truth is that where the policy indicates that individuals cannot be trusted with biological materials, equipment, and facilities, the foundation of the policy is one of distrust. Trust is essential to developing a culture of responsibility and accountability with biological materials and equipment if biosecurity is to be genuinely achieved by the global community.

The CBM of the BWC were first established to implement Articles V and X of the BWC at the Second Meeting of the Parties in 1986.[8] The Sixth Conference revived the mechanism and gave it new importance in the implementation and compliance aspects of the BWC.[9] This mechanism exemplifies trust in its objective — to build confidence. It would also

7. The President's News Conference With President Vladimir Putin of Russia in Kranj,1 PUB. PAPERS 685, 689 (June 16, 2001). "I found him to be very straightforward and trustworthy. We had a very good dialogue. I was able to get a sense of his soul . . . ." *Id*.

8. Second Review Conference of the Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction, *Final Declaration*, 2, 7, U.N. Doc. BWC/Conf.II/13/II (1986) [hereinafter Second Review Confrence], *available at* http://www.opbw.org/rev_cons/2rc/docs/final_dec/2RC_final_dec_E.pdf.

9. *See* Sixth Review Conference of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and On Their Destruction, *Final Document,* 12, U.N. Doc BWC/Conf.VI/6 (2006) [hereinafter Sixth Review Confrence], http://www.opbw.org/rev_cons/6rc/docs/6/BWC_CONF.VI_6_EN.pdf.

embrace the concept of dual use measures taken by a country, but is much broader in its options and possibilities. CBMs are difficult to assess for the public, however, because they are accepted with the promise of confidentiality, it makes them unavailable to the public where confidence could be further built.[10] CBMs encompass a broader vision of enforcement of the BWC by the possibilities that can be captured by a nation's culture and through legal traditions.

The first part of this article examines the politics of public health, its globalization in politics, and the rise in the need for biodiplomacy. The second part discusses globalized governance and the use of international law and biodiplomacy. The third part discusses an approach to biological weapons deterrence based on models of risk of those countries most likely to have bioweapons activities and threats. Finally, the article will finish with some views and research for the future.

II. PUBLIC HEALTH IN THE DIPLOMATIC AGENDA

The BWC, effective in 1975,[11] had a very simple but straightforward objective — to stop the production and possession of biological weapons by nations.[12] It came at the end of a biological arms race that was openly moving forward into a frightening future of cataclysmic biological warfare. President Nixon ended the U.S. biological weapons program in 1969,[13] triggering closure of biological weapons programs in other nations also known to have them. Biological weapons were seen as a national security concern, rather than a public health concern, which at the time, was focused on clean water and childhood vaccinations. Domestic policy was very far from foreign policy in the area of potentially deadly diseases at this point in the political history for the U.S.

The isolation of public health from foreign policy concerns about biological weapons meant that the U.S. considered public health to be "low

10. *See generally* Organization for the Prohibition of Chemical Weapons, Convention on the Prohibition of the Development, Production, Stockpiling and Use of Chemical Weapons and on their Destruction, Jan. 13, 1993, 1974 U.N.T.S. 45, annex, General Principles for the Handling of Confidential Information, at 161, *available at* http://www.opcw.org/chemical-weapons-convention/confidentiality-annex/ (describing general principles for handling confidential information).

11. *The Biological Weapons Convention,* U.N. OFFICE FOR DISARMAMENT AFFAIRS, http://www.un.org/disarmament/WMD/Bio/ (last visited November 13, 2013).

12. *Id.*

13. *General Article, Nixon Ends Biological Weapons Program,* PBS, http://www.pbs.org/wgbh/americanexperience/features/general-article/weapon-nixon-ends/ (last visisted November 13, 2013).

politics" in diplomatic negotiations.[14] These were issues that did not have priority, except for use as a type of political currency for trading for more important issues. Public health was typically helpful only to developing nations and regions of severe poverty, where poverty and lack of a public health infrastructure went hand-in-hand.

A change in this perspective was triggered by a series of events beginning with the post-9/11 attack, which used anthrax spores in letters sent to legislators and members of the media in 2001.[15] In 2003, the emergence of Severe Acute Respiratory Syndrome (SARS), which created a global pandemic with an uncontrollable spread of a highly contagious viral disease with no vaccine and no effective treatment,[16] was a stark realization that national security was potentially at risk. In 2004, the collapse of the negotiations for an inspection protocol for the BWC was largely led by the U.S., which left a void in the global view of how these weapons might be controlled.[17] Also around this time, it became evident that there had been a misappropriation with Iraq's weapons of mass destruction program,[18] which led to uncertainty in our ability to accurately assess the threat of biological weapons. Then, in 2008, the influenza vaccine shortage forced the U.S. to develop prioritization directives for which individuals would get the vaccine, presenting the problem of shortages of countermeasures.[19] The Swine Flu in Mexico, which started in 2008, was declared a pandemic by the WHO in June 2009[20] with an announcement from the WHO Director stating, "We have evidence to suggest we are seeing the first pandemic of the 21st

14. David P. Fidler, *Public Health and National Security in the Global Age: Infectious Diseases, Bioterrorism, and Realpolitik*, 35 GEO. WASH. INT'L L. REV. 787, 855 (2003).

15. *Id.* at 796.

16. *See id.* at 840.

17. *See* Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction, G.A. Res. 59/110, ¶ 3-5, U.N. Doc. A/RES/59/110 (Dec. 3, 2004).

18. *See* Congresswoman Jane Harman, Ramking Member on the House Permanent Select Committee on Intelligence, The Intelligence on Iraq's WMD: Looking Back to Look Forward, Remarks before Los Angeles World Affairs Council (Feb. 16, 2004), *available at* https://www.fas.org/irp/congress/2004_cr/harman011604.html.

19. *See* CTRS. FOR DISEASE CONTROL & PREVENTION, CONTINUED SHORTAGE OF HAEMOPHILUS INFLUENZAE TYPE B (HIB) CONJUGATE VACCINES AND POTENTIAL IMPLICATIONS FOR HIB SURVEILLANCE—UNITED STATES 2008, 1 (2008).

20. Margaret Chan, M.D., Director-General, World Health, World Now at the Start of 2009 Influenza Pandemic, Statement to the Press 1 (June 11, 2009), *available at* http://www.who.int/mediacentre/news/statements/2009/h1n1_pandemic_phase6_20090611/en/index.html. *See also The 2009 H1N1 Pandemic: Summary Highlights, April 2009-April 2010*, CTRS. FOR DISEASE CONTROL & PREVENTION, http://www.cdc.gov/h1n1flu/cdcresponse.htm (last updated June 16, 2010).

Century."[21] This was a striking reminder that resources could be challenged and national security may be at risk if an unexpected pandemic emerges.

The rise of public health emergencies and the *realpolitik* of their effect on national security slowly became evident over the course of these events. But there was resistance to seeing national public health preparedness and response as anything other than a public health area of sovereignty for the states that was not to be encroached. Public health security responsibility was not something that the Department of Defense (DOD) wanted to assume. Clear evidence of this resistance can be seen in the action taken by the DOD immediately following the first anthrax attack, when the need to purchase antibiotics as a countermeasure was seen as a national defense need and for emergency defense procurements; the DOD provided the most ready mechanism. But in order to make purchases of the antibiotics, the anthrax attacks had to be classified as a threat to national security, and the DOD declined. This action would have enabled them to place antibiotics on the list of items that they could procure through defense purchases. Instead, the Department of Health and Human Services (HHS) became the lead on responding to the need to purchase Cephalexin™ and amoxocillin, the two recommended drugs.

Once the immediate need for antibiotics to treat anthrax exposure was met, Congress and the President turned to the problem of readiness for the next possible attack. A shift from the states to the federal government for national preparedness for national security never took place. HHS reorganized to establish a structure that could respond to national public health preparedness and emergencies.[22] The NIH was given a research mandate that came with nearly $3.5 billion to immediately begin research and develop countermeasures.[23] Both the short-term emergency preparedness needs and the long-term research strategies were implemented and represented as an incremental shift in federalism responsibility from the states to the federal government. The regulations that would follow for biosecurity would continue the shift to federal regulation of public health in particular areas, such as emergency releases.

The resistance to moving any of the public health responsibility from the states to the federal government was also evident in the Department of

21. *WHO Declares Swine Flu Pandemic,* BBC NEWS, (June 11, 2009, 9:51 PM), http://news.bbc.co.uk/2/hi/8094655.stm.

22. *HHS Reorganizes Bioterrorist Response Strategy*, CAL. HEALTHLINE (Nov. 8, 2001), http://www.californiahealthline.org/articles/2001/11/8/hhs—reorganizes-bioterrorist-re sponse-strategy.

23. *See* Anthony S. Fauci, *Bioterrorism: Defining a Research Agenda*, 57 FOOD & DRUG L. J., 413, 416-17 (2002); Luciana L. Borio & Gigi Kwik Gronvall, *Anthrax Countermeasures: Current Status and Future Needs*, 3 BIOSECURITY & BIOTERRORISM: BIODEFENSE STRATEGY, PRAC. & SCI., 102, 105 (2005).

Homeland Security (DHS), which had been "stood up" in 2003. Little attention was noted on the fact that nothing about the new DHS would address the anthrax attacks, which had been partially responsible for the movement to protect homeland security and the reorganization of the federal government into a DHS. Instead, DHS focused only on areas with existing federal jurisdiction, like agriculture and food, not public health, which still stayed rooted in state sovereignty, but incremental changes continued to push that norm.

As experiences in public health emergencies increased over the decade, they were viewed from the *realpolitik* perspective on national security. Simply put, international cooperation on public health matters became expedient when it contributed to the state's national security.[24] The U.S. had begun to think of national security in terms of economics; even public health was seen through an economic lens. Interest in trade required an investment in public health responses to diseases that might be either spread through trade and travel or that might prevent the free flow of trade. Interest in supporting nations in need of public health resources remained particularly high where the U.S.'s assistance could preclude unfriendly nations from developing alliances from their support. Investments in the public health of other nations also became important to the protection of trade and to making investments in the support of countries' public health infrastructure.

The U.S. has participated in global health since the 1800s, most recently through the WHO Assemblies which tend to focus narrowly on the diseases that are most threatening.[25] The list of reportable diseases among the WHO member nations included only smallpox, cholera, and plague,[26] and when these became rare, this mechanism of public health cooperation fell into disuse. There was very little need for it.

Then, beginning in the 1970s, a dramatic change occurred in international travel. As air travel become more affordable, travel to international destinations increased approximately 400% between 1970 and 2005.[27] This had the inevitable effect of also increasing the travel of viruses and bacteria by approximately 400%, making it possible for any disease to travel around the world in less than 24 hours. The International Health Regulations (IHR) from 1969, were dusted off, and a plan to revise them

24. Fidler, *supra* note 14, at 841.

25. *See* Michael McCarthy, *A Brief History of the World Health Organization*, 360 LANCET 1111 (2002).

26. *See generally* Joseph B. Greene, *Report from Berlin – Plague, Smallpox, and Cholera in Various Countries*, 16 PUB. HEALTH REPORTS 782, 782-83 (1901) (explaining that these three disease were prevalent in the early 1900s).

27. *See* JEAN-PAUL RODRIGUE ET AL., THE GEOGRAPHY OF TRANSPORT SYSTEMS (3d ed. 2013), http://people.hofstra.edu/geotrans/eng/ch7en/appl7en/ch7a3en.html.

was put into place after the SARS pandemic in 2003.[28] By 2005, the revised IHRs,[29] which were now binding on WHO member nations, stood ready to address newly emerging pandemics and threats of pandemics.

The U.S. was criticized by some Americans because it allowed the WHO to dictate policy of public health management to a sovereign nation.[30] Other member nations had agreed to the same diminishment of sovereignty for the greater good; however, many nations feared this would open control of their domestic affairs and sovereign control over them to outside powers such as the U.S.[31] Russia and China were particularly concerned.[32] The interest in engaging with other nations for public health emergencies requires the U.S. to develop a biodiplomacy policy. This must consider not only the economics of providing public health resources, but to do so with an eye toward the self-interests of other nations in protecting their own sovereignty and maintaining control over their domestic affairs.

It is clear that global biosecurity, including global public health and threats to national security, have pushed these issues into the "high politics" agenda of international diplomacy from its "low politics" status of just a few decades ago. The need to develop a diplomatic strategy to address this new heightened concern for national security, because of global public health threats, encompasses this emerging concept of biodiplomacy. Such a concept will serve the goals of the U.S. in accomplishing its diplomatic objectives, driven by *realpolitik*.

III. SIX TRENDS THAT ARE DRIVING BIODIPLOMACY

There are six trends that have pointed to a cohesive strategy of biodiplomacy as an essential tool for global governance. It is distinguishable from diplomacy because it requires an expertise and knowledge of specific biological diplomatic histories, landmarks, and timelines, as well as cultures that lead to special insights and advice. Diplomatic skills are consistently

28. *Ten Things You Need to Do to Implement the IHR*, WORLD HEALTH ORG. http://www.who.int/ihr/about/10things/en/ (last visited Oct. 17, 2013).

29. *Id.*

30. Rob Stein, *WHO Gets Wider Power to Fight Global Health Threats*, WASH. POST, May 28, 2003, at A15. Stein reported that the actions by the World Health Organization "mark the first significant expansion of WHO's power in more than three decades." WHA56.28 "frees [the] WHO from having to wait until a country officially reports an international health threat before beginning countermeasures . . . and gives the agency the authority to begin ground inspections without a formal invitation." *See also* World Health Org. [WHO], *Revision of the International Health Regulations*, WHA Doc. WHA56.28 (May 28, 2003), *available at* http://apps.who.int/gb/archive/pdf_files/WHA56/ea56r28.pdf.

31. *See* Fidler, *supra* note 14, at 845-46.

32. *Id.*

called for in such a strategy, but they cannot be relied upon as a singular tool to address global biosecurity.

Increasingly, nation-states and the global community are cognizant of a change in risk to the health of its people. It is becoming the normative understanding among nations that any infectious disease is not just one country's problem. These trends have led to a new norm in understanding and recognition of this need. The following six concepts contribute to this overall shift.

A. Global Public Health Commons

The term "global public health commons" is an extension of the concept of the environmental global commons.[33] The environmental global commons is the shared air that we breathe and the shared water through the water cycle — those natural resources that are held in common by all nations in the world. The water cycle, for example, does not recognize jurisdictional borders, nor can nations control the water cycle and its redistribution of water wealth through droughts and floods. So, too, infectious diseases and the vectors of infectious diseases (i.e., rats and birds) do not recognize the jurisdictions of nations and cross borders freely on food, animals, or humans. They wander freely and infect evolutionarily. A global public health commons is a dimension of human contact that defines the global public health commons which can also be the water cycle and the air. These commons can also be defined as spaces, such as the airspace of air travel where governmental jurisdictions change throughout the journey, crossing from one country to the next.

These concepts were captured in the IHR, crafted to focus on infectious diseases and the establishment of normative behaviors of nations when such infectious diseases pose threats to other nations. The IHR of 2005 is reliant on diplomacy to affect many of its provisions, for example, the request for assistance must come from the nation to the WHO, and this requires ongoing dialogues with parties to the IHR in order to maintain communication to make such notice to the WHO more likely.[34]

33. *Res communes,* first articulated in the Supreme Court opinion Geer v. Conn., 161 U.S. 519, 525 (1896), defined as "those things which were common to all belonged no more to one than to the others." *See also* Owen J. Lynch & Greg Maggio, *Human Rights, Environment, and Economic Development: Existing and Emerging Standards in International Law and Global Society*, CTR. FOR INT'L ENVTL. LAW (1998), at § IV, *available at* http://www.ciel.org/Publications/olp3iv2.html. The term "common heritage of mankind," has also become a norm in international law.

34. *See* WORLD HEALTH ORG., INTERNATIONAL HEALTH REGULATIONS (2005) (2nd ed. 2008) at 12, *available at* http://whqlibdoc.who.int/publications/2008/9789241580410_eng.pdf. "The purpose and scope of the IHR (2005) are 'to prevent, protect against, control and

B. Increased Air Travel, Refugees, and Mass Gatherings

The precipitating factor in increasing opportunities for the spread of infectious diseases was certainly the explosion in international air travel, which increased 400% since the 1970s.[35] Although it was unproven, the rapid spread of HIV/AIDs in the 1980s was attributed to air travel, and one flight attendant, fueling the fear that diseases could be transported via air travel.[36] The idea that air travel was a vehicle for the beginning of deadly epidemics became a harsh reality by the end of the Twentieth Century. Beginning in the second millennia, in 2003, SARS was rapidly disseminated around the globe through air travel in a matter of days and to more than two dozen countries around the globe in two months.[37]

The frequency of mass gatherings is also growing. The traditional Hajj has historically involved public health planning for a large gathering of people traveling thousands of miles to Saudi Arabia.[38] Lessons from these early mass gatherings have been applied to Olympic events, other major sports events, religious pilgrimages, and political gatherings.[39] The WHO has developed an expertise in this field through a cadre of experts who assist in planning these events, and diplomacy is vital to its success.[40] The need to alter local public health and safety codes, and the necessary infrastructure to ensure safe food, water, and building capacity in response to public health emergencies is the type of emerging diplomacy which comes under the label of biodiplomacy, capturing the spirit of assisting for public health emergencies with a commitment to leave the nation better off than without the planning assistance.[41]

Refugees, too, are increasing. Refugee camps are in close proximity with makeshift sanitary conditions and infrastructure. Because of the need to

provide a public health response to the international spread of disease'" in part by requiring State Party's to develop "certain minimum core public health capacities."

35. *See* JEAN-PAUL RODRIGUE ET AL., *supra note* 27.

36. *See generally* David M. Auerbach et al., *Cluster of Cases of the Acquired Immune Deficiency Syndrome*, 76 AM. J. MED. 487, 489, 490 (1984) (clarifying that the flight attendant mentioned was Patient 0 who attributed to the rise in HIV/AIDS in the 1980s to do promiscuous behavior).

37. Alexandra Mangili & Mark A. Gendreau, *Transmission of Infectious Diseases During Commercial Air Travel*, 365 LANCET 989, 992 (2005). *See* CTRS. FOR DISEASE CONTROL & PREVENTION, FACT SHEET: BASIC INFORMATION ABOUT SARS 1 (2004).

38. Qanta A. Ahmed et al., *The Quest for Public Health Security at the Hajj: The WHO Guidelines on Communicable Disease Alert and Response During Mass Gatherings*, 7 TRAVEL MED. & INFECTIOUS DISEASE 226, 228 (2009).

39. *Id.* at 227.

40. *See id.*

41. *See* WORLD HEALTH ORG., REPORT ON WHO SUPPORT TO THE 2010 FIFA WORLD CUP SOUTH AFRICA (2011).

address displaced persons due to war, the United Nations High Commissioner for Refugees (UNHCR) was formed by the United Nations (U.N.) to find practical solutions to the increasing problem of refugee populations with its new diplomatic authority.[42] Refugee camps were becoming permanent communities, but lacked sewer and water infrastructures, making them opportunities for cholera outbreaks and other opportunistic diseases. The number of refugee camps is growing, while the return or permanent placement of refugees has scarcely been attempted.[43] This activity is outside the other WHO agencies and has displaced persons as its priority, but there is no doubt that public health emergencies must be dealt with diplomatically, seeking cooperation and assistance from member nations.

C. Biotechnology Revolution, Genetically Modified Organisms, and Increasing Research

Genetic engineering of all types and the isolation of bioregulators, which affect human physiological function and the explosion in the use of synthetic biology by the public, are unaddressed in any security regime. The concept of dual use in narrow application to research does not adequately capture these emerging areas of scientific research and the possibilities for good as well as harm. Biodiplomacy is called for to maintain communication and collaboration at the highest levels, from the bench scientist level to law enforcement to ensure common goals of public health and safety. This kind of diplomacy is based on trust and the culture of science in sharing information and scientific resources.

Collaboration with scientists in foreign laboratories has raised questions about the biosecurity and biosafety of their laboratories, particularly when working with select agents — those biological materials with potential dual use. The grants from NIH were made conditional to meet certain biosafety and biosecurity requirements, and the CDC was tasked with developing a compliance protocol.[44] However, the effort to have the CDC inspect laboratories before the scientists in foreign laboratories could work with U.S. scientists raised concerns that the U.S. was seeking to extend its jurisdiction

42. U.N. High Comm'r for Refugees, An Introduction to International Protection: Protecting Persons of Concern to UNHCR, at 7 (Aug. 1, 2005), http://www.unhcr.org/3ae6bd5a0.pdf.

43. U.N. High Comm'r on Refugees, UNHCR Global Trends 2012: Displacement The New 21st Century Challenge, at 35 (June 19, 2013), http://unhcr.org/globaltrendsjune2013/UNHCR%20GLOBAL%20TRENDS%202012_V05.pdf; U.N. High Comm'r on Refugees, UNHCR 2009 Global Trends: Refugees, Asylum-seekers, Returnees, Internally Displaced and Stateless Persons, at 2-3 (June 15, 2009), http://www.unhcr.org/4c11f0be9.html.

44. *See* NAT'L INST. OF HEALTH, NIH GRANTS POLICY STATEMENT IIA-34-IIA35 (Oct. 2012). *See* 42 U.S.C. § 262a(c) (2011).

outside of the U.S. by exerting regulatory authority over laboratories in other sovereign jurisdictions.[45] While the reality is that this is simply a condition for receiving grant money, the perception of the U.S. intruding on other nations' sovereignty called for a better biodiplomatic strategy to demonstrate that this was not an attempt by the U.S. to extend jurisdictional authority outside U.S. borders. This is another example of where biodiplomacy and its unique needs have not been fully met.

Restrictions on publication of what is considered to be biological research that might be used by terrorists has raised concerns that the Constitutional First Amendment,[46] freedom to publish, was too heavily burdened by attempts to restrict publication. If free speech is to be burdened, there is a high threshold to meet to show that the publication is a threat to national security. However, efforts were also made to restrict authors outside the U.S. from gaining knowledge by editing their articles in the U.S., and making a determination that this was a "deemed export" for purposes of restricted exports to listed countries under the U.S. Arms Export Control Act.[47] Eventually, Secretary Condoleezza Rice announced that a previous Executive Order prevented restricting the free exchange of scientific information, and the rule was narrowed.[48] However, in 2013, the definition of "dual use technologies" under three import-export regimes in the U.S. complicated and confused maintaining trade and research relations with other nations and companies.[49] Dual use technologies as a defined category has not provided clarity in this regulatory regime of import and export processes, and ultimately, other criteria will need to be developed. The categorization of dual use technologies is also based on an assumption of ill intent and sends a message of mistrust. The failure of biodiplomacy in these cases caused a considerable loss of good will among scientists.

45. NAT'L INST. OF HEALTH, NAT'L INST. OF ALLERGY & INFECTIOUS DISEASES, SELECT AGENT POLICY FOR FOREIGN INSTITUTIONS, http://www.niaid.nih.gov/researchfunding/qa/pages/selagentfor.aspx (last updated Jan. 9, 2013).

46. U.S. CONST. amend. I.

47. CONTROL OF ARMS EXPORTS AND IMPORTS, 22 U.S.C. § 2778 (2011); Benjamin Carter Findley, *Revisions to the United States Deemed-Export Regulations: Implications for Universities, University Research, and Foreign Faculty, Staff, and Students*, 2006 WIS. L. REV. 1223, 1229, 1241-42 (2006).

48. Jessica Stern, *Dreaded Risks and the Control of Biological Weapons*, 27 INT'L. SECURITY, Winter 2002-2003, at 117.

49. *See* Position Statement, IEEE-USA, Reforming Technology Export Controls and Deemed Export Policy (Sept. 19, 2012) *available at* http://www.ieeeusa.org/policy/positions/ExportControls0912.pdf.

D. Modern Bioterrorism

The U.N.'s process for filing complaints regarding the use of biological weapons has never been used. However, the consultative process has been the choice of nations in resolving disputes. Cuba, for example, has brought 22 complaints of the use of biological terrorism by the U.S. without utilizing the formal process.[50] Why has this mechanism never been used, and why has the consultative method been utilized? The U.N.'s process for making formal complaints has all but ensured that no one will ever file a complaint.

The BWC lacks an inspection and verification protocol, which led to the development of Confidence Building Measures (CBM) after failing to reach an agreement on an inspection protocol.[51] CBM is an example of biodiplomacy.

The use of the U.N. Security Council Resolution (UNSCR) 1540 mechanism has been the result of biodiplomatic efforts to respond to a gap in the BWC,[52] which lacks a verification mechanism. The UNSCR 1540 mechanism was utilized in the inspection of the Iraq biological weapons program after significant intelligence led the U.N. member states to conclude that there was still such a program underway in Iraq.

E. Emerging Infectious Diseases

Emerging infectious diseases have always been with us, but a number of factors, like the increase in international travel, increase in population density, and the close exposure to animals with humans, have made emerging infectious diseases possible. Disrupting habitats of some of the richest biodiversity areas in the world causes migration and movement of species that have been isolated, risking viral mutations and species-jumping of viruses, which brought us such deadly viral diseases such as SARS, bird flu, and the Nipah virus.[53] In order to conduct surveillance globally, diplomacy is required to ensure ongoing communication and the transmission of findings in a context of trust. Gathering surveillance information from state governments in the U.S. is so difficult that the U.S. still lacks a national disease surveillance system, hampered by our system of

50. Elisa D. Harris, TERRORISM, WAR, OR DISEASE? UNRAVELING THE USE OF BIOLOGICAL WEAPONS 223 (Anne L. Clunan et al. eds., 2008).

51. Marie I. Chevrier, *Doubts About Confidence: The Potential and Limits of Confidence Building Measures for the Biological Weapons Convention*, *in* THE HENRY L. STIMSON CENTER, BIOLOGICAL WEAPONS PROLIFERATION: REASONS FOR CONCERN, COURSES OF ACTION 52, 56 (1998).

52. *See* James D. Fry, *Dionysian, Disarmament: Security Council WMD Coercive Disarmament Measures and Their Legal Implications*, 29 MICH. J. IN'L L. 197, 243-44 (2008).

53. *See* M. L. Flanagan et al., *Anticipating the Species Jump: Surveillance for Emerging Viral Threats,* 59 ZOONOSES & PUB. HEALTH 155, 157 Table 1(b) (May 2011).

federalism that has yet to yield to the demands of modern transportation of diseases.[54] The difficulty in asking sovereign nations for their surveillance data is equally, if not more so, a demand on diplomatic skills. Understanding the science and reasons for the need for this surveillance data is captured by the biodiplomacy concept.

The continuing loss of our arsenal of antibiotics and the few anti-virals against diseases with antibiotic resistant organisms, and the still slow development of vaccines in response to emerging diseases has further complicated our ability to be prepared, but increased our need for diplomacy in a context of trust.

F. Public Health Disasters and Environmental Disasters

Biodiplomacy is essential to get the right kind of help for environmental disasters. A failure to use biodiplomacy can compound the disaster if the advice is not timely, biased for political purposes, or fails to follow international norms and laws. Failures of responding to public health disasters may be the result of poor planning, deficient or non-existent public health infrastructure in the country, or uncertainties in governance as to who is responsible for what.

IV. GLOBAL GOVERNANCE AND THE USE OF INTERNATIONAL LAW AND BIODIPLOMACY

The DURC program in the U.S. focuses on a culture of mistrust, which is counterintuitive to the research community that has always been built on a culture of sharing, trust, and openness. By targeting equipment and biological agents for dual use determinations through treaties and domestic laws, the importance of process is overlooked. Translating DURC to the international community spreads the culture of mistrust that comes with the concept.

Moves toward globalized governance exist when common concerns in global public health commons cannot be effectively addressed through sovereign spheres of action alone. Shared governance in a global quasi-jurisdiction are pushed forward, yet it relies almost exclusively on the sovereignty of nations to use their sovereign powers of civil and criminal law, and enforcement to address the individuals who might engage in illegal activities.

The term "dual use" can quickly become diluted and lose its focus. Essentially the double-edged sword analysis of each of these applications

54. Victoria Sutton, *BIOTERRORISM: Bioterrorism Preparation and Response Legislation—The Struggle to Protect States' Sovereignty While Preserving National Security,* 6 GEO. PUB. POL'Y REV. 93, 94-95 (2001).

demonstrates the problem. Some examples are: (1) Transportation Security — commerical aircraft can become deadly killing machines; (2) Cybersecurity — the Internet can be used for vital life-saving communication, but also used to shut down a nation's power-grid, and air traffic control system; (3) Nuclear Security — uranium enrichment facilities can be used to fuel nuclear power plants, but they can also be used to fuel nuclear warheads (at a higher quality); (4) Biosecurity — biotechnological fermenters can make babyfood as well as bioweapons.

Realpolitik predicts that the most urgent of these will rise to the top of the diplomatic agenda in meetings and negotiations as immediate national security concerns. But there are important differences between biosecurity and the other threats in the preceding examples.

By far, the dual use of uranium enrichment by Iran has been at the top of the diplomatic agenda and in the news more than any other issue, and the focus is on its dual use. Graham Allison, the founding Dean of Harvard's John F. Kennedy School of Government and a leading expert on nuclear proliferation, told a *New York Times* reporter:

> Nuclear terrorism is a preventable catastrophe, and the reason it's preventable is because the material to make a nuclear bomb can't be made by terrorists. But in the bio case — oh, my God! Can I prevent terrorists from getting into their hands anthrax or other pathogens? No! Even our best efforts can't do that.[55]

A report by the Congressional Commission on the Prevention of Weapons of Mass Destruction Proliferation and Terrorism concluded: "To date, the U.S. government has invested most of its nonproliferation efforts and diplomatic capital in preventing nuclear terrorism. The commission believes that it should make the more likely threat — bioterrorism — a higher priority."[56]

Biodiplomacy, then, is unique and requires risk communication, threat assessment, and comparative risk among the set of skills, as well as knowledge of the biosafety and biosecurity history of regulation and treaties, which also requires a reasonably good knowledge of the life sciences in this context. Diplomatic assignments should include a specialized staff assignment for biodiplomacy with these requisite skills. The moniker of "dual use" can only serve a limited purpose in addition to the damage it creates by the negative distrust that is generated by the assumptions of the term.

55. Wil S. Hylton, *How Ready Are We for Bioterrorism?*, N.Y. TIMES MAG., Oct. 26, 2011, *available at* http://www.nytimes.com/2011/10/30/magazine/how-ready-are-we-for-bioterrorism.html?pagewanted=all&_r=2&.

56. THE COMM'N ON THE PREVENTION OF WEAPONS OF MASS DESTRUCTION PROLIFERATION AND TERRORISM, WORLD AT RISK 24 (1st ed. 2008).

The problem of dual use is captured in a popular medium of this political cartoon,[57] demonstrating that there are a wide range of dual use definitions that can dilute and make ineffective the use of the term "dual use" in a culture built on trust.

V. FOCUS ON REALPOLITIK ISSUES BY MAKING RISK-BASED DECISIONS IN A CONTEXT OF TRUST

Since the interpretation of world governance through the beginnings of international law, the recognition of nations' sovereignty was made clear.[58] The acceptance that the world would be governed by a collection of nations and that power would be held by the nation-state has centered power over individuals in the sovereign jurisdiction of nations. International governance continues to be enforced primarily through diplomatic pressure and politics in the framework of a collection of treaties. Sovereign nations' strength of the rule of law provides domestic enforcement of international norms. But the strength of the rule of law varies so much from one nation-state to another that domestic law enforcement is not a sufficient approach. This alone challenges the notion that dual use as a criteria for enforcement

57. Eldon Pletcher, *Iran's Uranium Enrighment Program is Strictly for Medical Resear. . .Oops!, available at* http://www.cartoonstock.com/newscartoons/cartoonview.asp?catref=epln1434.

58. *See* HUGO GROTIUS, THE RIGHTS OF WAR AND PEACE 62 (A.C. Campbell trans., 1901) (1625).

cannot operate in a country with a weak rule of law or where the strength of the rule of law is uncertain or insufficient.

During the BWC's Second Meeting, a decision was made to utilize CBMs to implement Articles V and X of the BWC.[59] This was followed by a re-invention of a mechanism to report CBMs in the Sixth Meeting.[60] These reported activities by member nations about their activities, including the passage of domestic laws, are mandatory to ensure compliance with the BWC and engender confidence in their full compliance. A wide range of activities could qualify as long as they are intended to bring confidence and assurances of compliance. Dual use oversight is a more narrow focus within the CBMs. The U.S., for example, would include the DURC program among the CBMs in carrying out their obligations under the BWC. Some of these, like the DURC program, would qualify as a CBM: (1) Biosafety and Biosecurity Regulations, CDC, 42 CFR §73; (2) DURC program; (3) Transportation regulations for shipment of select agents, Department of Transportation; and (4) Import-Export Programs regulating dual use technologies and materials, the DOD, International Traffic in Arms Regulations list and the Department of Commerce commercial list.

Although the CBMs are submitted with an agreement of confidentiality for attribution to the particular nation, the BWC Administrative Unit has published a list of the categories and types of measures taken under the CBM requirement without making specific attributions. This list of the status of implementation of the BWC documents that 18 of the 190 members had implemented measures to address dual use biological equipment and related technology.[61] Import controls were the widest single mechanism used to control the threat of biological weapons.[62] Fifty-nine member countries require authorization for export and import of dangerous biological agents and toxins.[63] While these are impressive, it falls far short of compliance by the 190 members — less than one third of the members have complied with the CBMs as a general observation from this data — and much of this may be attributable to the range of the strength of the rule of law in the member nations.[64]

The strength of the 141 weakest nations has been measured and ranked by the Brookings Institution using 20 factors in their report, one of which is

59. Second Review Confrence, *supra* note 8, at 7.

60. *See* Sixth Review Confrence, *supra* note 9, at 12.

61. *See* Seventh Review Conference of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction, *Final Document of the Seventh Review Confrence*, 1, U.N. Doc. BWC/Conf.VII/INF.8 (2011).

62. *See id.*

63. *See id.*

64. *See id.*

the strength of the rule of law.[65] Capability and instability criteria can be gathered from the World Bank Index.[66] The World Bank Index of the regulatory quality of nations[67] — a measure taken annually since 1996 — is one criterion for the reliability of that nation to administer a dual use program of its biological activities, ranging from baby food to pharmaceuticals.

One researcher combined other criteria that ranked measures of biotechnological skills, commercial development, and facilities as a method for identifying nations with capacity to develop biological weapons.[68] This study created a four tier ranking of countries with biotechnological capability as a way of assessing the dual use concerns.[69] The tiers were created using stability factors with "biotechnological potential."[70] The report describes these tiers with examples:

> Tier 1: Dominant biotechnology countries — "The West:" U.S., Europe, Russia and offshoots (Japan, Australia).
>
> Tier 1A: Nations in developing world with significance biotech growth potential — India and China.
>
> Tier 2: Countries with some biotechnology human and physical capabilities — Israel, South Korea, Brazil, South Africa, Nigeria, Kenya, Singapore, Thailand, UAE, Dubai, Algeria, Egypt, Malaysia, Cuba, Sudan, Pakistan, Iran, North Korea.
>
> Tier 3: Countries with an interest but with little chance of developing civilian biotechnology commercial activities — The rest of Latin America, Asia-Pacific, Africa (island states, Mauritania, Caribbean states, Tanzania, Eritrea).
>
> Tier 4: Collapsed States — Democratic Rep Congo; Somalia.
>
> *Note: The listed countries are designated to illustrate the type of countries in each category. This is not an exhaustive list of all countries with some biotechnology potential.[71]

65. SUSAN E. RICE & STEWART PATRICK, THE BROOKINGS INSTITUTION, INDEX OF STATE WEAKNESS IN THE DEVELOPING WORLD 3, 8 (2008).

66. THE WORLD BANK, WORLD DEVELOPMENT INDICATORS: FINANCIAL ACCESS, STABILITY AND EFFICIENCY tbl. 5.5 (2013), *available at* http://wdi.worldbank.org/table/5.5.

67. *See The Worldwide Governance Indicators (WGI) Project,* THE WORLD BANK, http://info.worldbank.org/governance/wgi/index.aspx#home (last visited November 14, 2013).

68. *See* HELEN E. PURKITT, BIOWARFARE LESSONS, EMERGING BIOSECURITY ISSUES, AND WAYS TO MONITOR DUAL-USE BIOTECHNOLOGY TRENDS IN THE FUTURE (2005).

69. *See id.* at 50 tbl 1.

70. *Id.* at 49-50.

71. *Id.* at 50.

Using the combination of the data of the 141 weakest nations from the Brookings Institution, along with the regulatory quality ranking of the World Bank Index, and the biological capability tiers, a risk assessment for potential biological weapons programs or non-state actors can be identified.

Targeting nations that are unlikely or unable to enforce dual use programs because of the lack of strength of the rule of law and weak governments can be identified through research and targeted for assistance rather than imposing impossible standards for compliance with the BWC.

VI. FUTURE CONSIDERATIONS

Early indications of this preliminary research of this data reveal some interesting propositions for utilizing a biodiplomacy concept. First, of the 141 weakest nations in the Brookings Institution, the countries likely to have biological weapons programs, or be host to such activities, were almost exclusively in the bottom 50% of the weakest governments.[72] Not only does this predict weak compliance with dual use criteria and the BWC, but it also supports the notion that biological weapons may be attractive as an "equalizer" for individuals in that nation or the nation itself. At any rate, weak governments are powerless to control these activities or safeguard its own research. More research is needed to correlate this data with "biological capabilities" identified through the tier ranking; for example, for better targeting for assistance, perhaps to implement Article X of the BWC.

Another observation from this preliminary research is that of those countries suspected of having bioweapons programs or activities not in the bottom 50%, they had been open to inspection and destruction of these weapons (i.e., Libya); their government had collapsed (i.e., Egypt); or they went through a government and judicial cleansing, including a special judicial proceeding around their bioweapons program (i.e., South Africa).

The political theory of *realpolitik* is where decisions are driven by political expediency and economics drives the importance of a concept of biodiplomacy, with the new concerns of public health moving from low politics to high politics. But it is still political expediency and national security driving the agenda, not concern for global public health.[73]

Biodiplomacy has some unique attributes that are just beginning to be appreciated as a distinct set of skills and goals. The strategy of approaching nations at the highest risk of being threats to global public health, because of the combination of factors indicating biological capacity with indicia of governmental instability and a weak rule of law in the context of past

72. *See* RICE & PATRICK, *supra* note 66, at 10-11.

73. Fidler, *supra* note 14, at 837.

examples of the nations of highest risk for biosafety and biosecurity breaches, suggests more studies should be done along these lines. Dual use criteria cannot reach these nations of highest concern.

The use of biodiplomacy to cast a broad net over issues that may prove to be threatening to national and global security in the context of building diplomatic relationships and trust will engender collaborative and collective communication among the specialized individuals in the life sciences and clarity among nations, both with the strongest to the weakest rule of law governments. Biodiplomacy can establish a process of engagement that would engender trust rather than institutionalizing distrust through dual use concepts among many nations that have no capacity to enforce its criteria.